

Evaluation of the instructions for reuse

Beware when buying



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Introduction



National Institute for Public Health and the Environment

- Our mission is to benefit people, society and the environment, matching our expertise, knowledge and research with that of colleagues from around the world
 - 1400 employees
 - Annual turnover >100 M€
- Vaccine production
- Environment
- Medical technology
- Research based advise to Ministry and Inspectorate

Medical Technology Section

- Prevention of disease transmission; cleaning, disinfection, sterilisation
- Human tissues, animal tissues and Tissue Engineering
- Assessment of technical documentation according MDD
- Biocompatibility - biomaterials
- Emerging Technologies, e.g. nanotechnology
- Public Health Forecast
- Reimbursement system
- Standardisation

What will I talk about?

- The reprocessing of reusable medical devices
- How to get the instructions you need to do that
- A checklist and a team of experts
- Conclusion



Transport



Use



Sterile Storage



Transport



Sterilization



Cleaning/ Disinfection



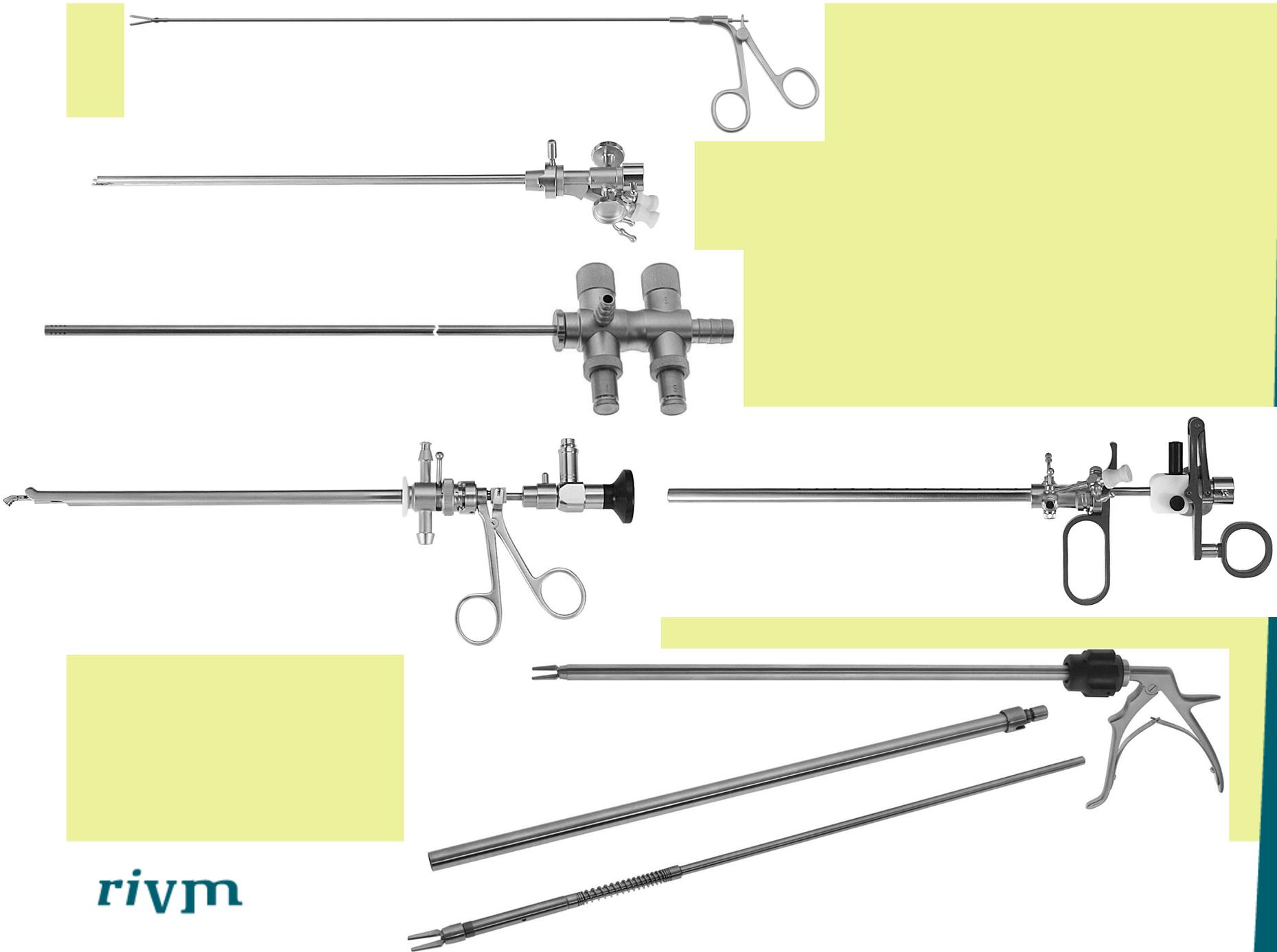
Packaging

Inspection & Tray Assembly

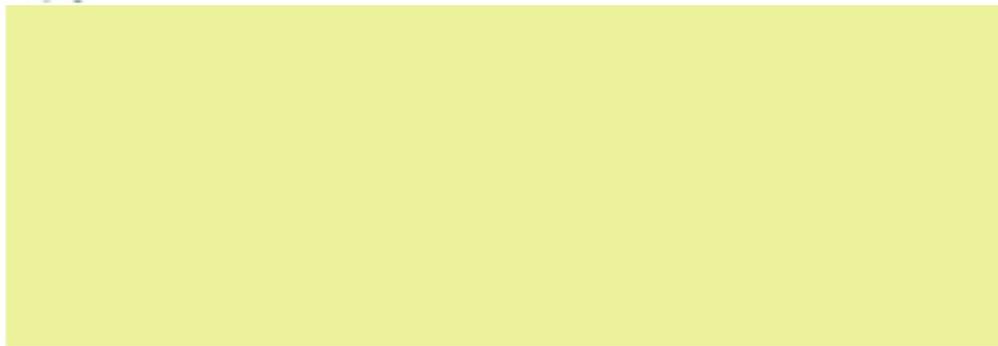
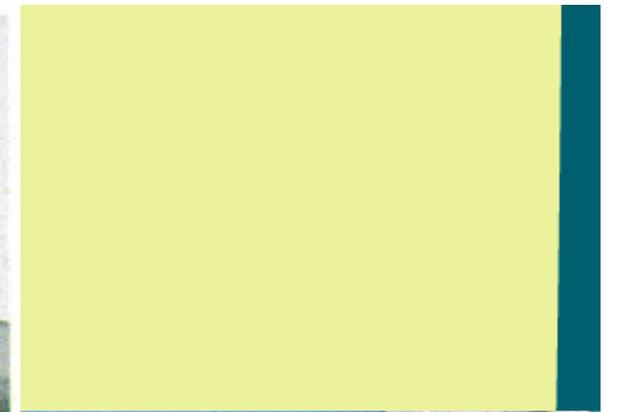
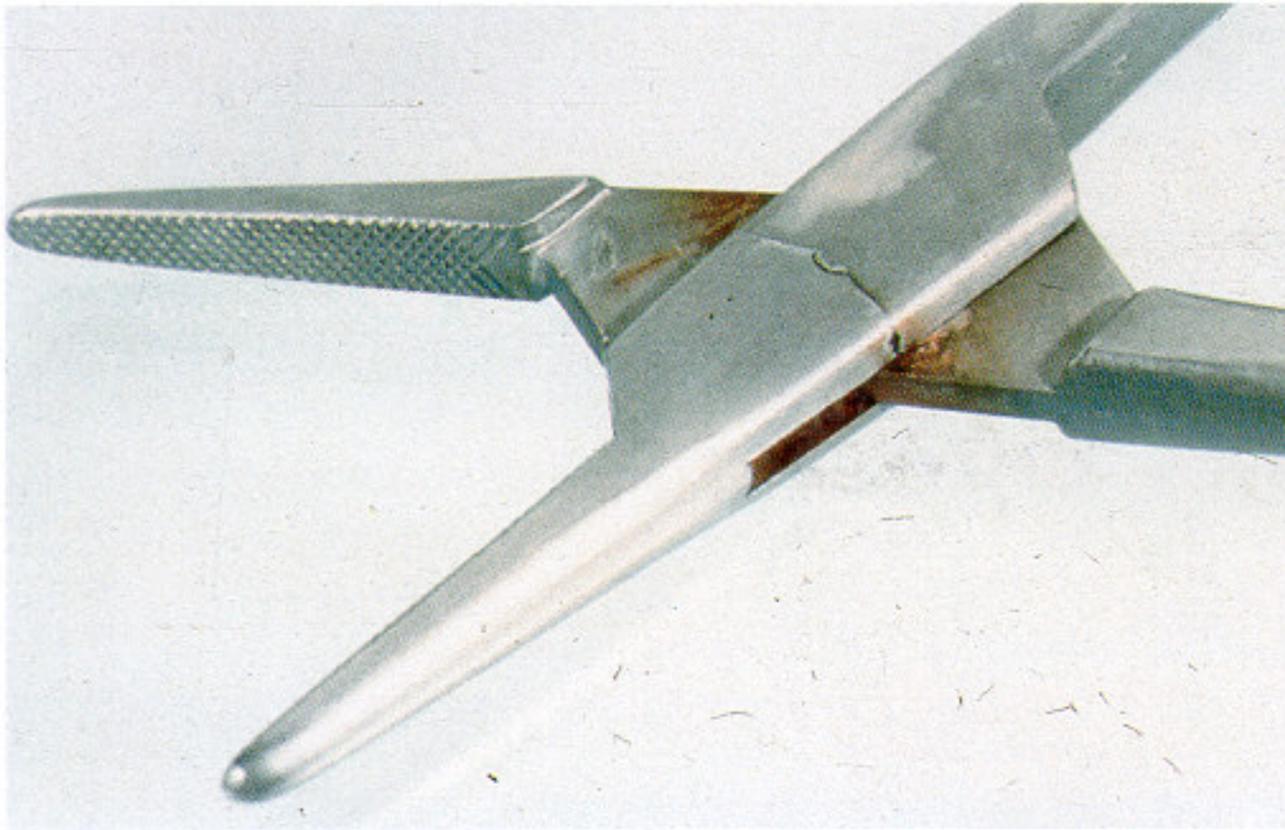


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Caveat emptor



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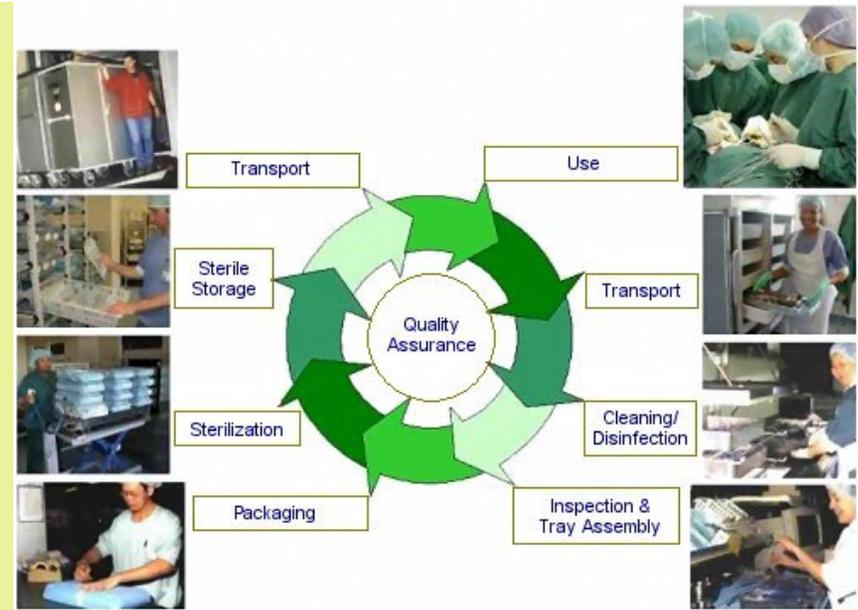


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Caveat emptor

Instructions for reuse

- Medical Device Directive demands that instructions for reuse must be provided for all resterilizable medical devices



- 13.6(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.
- However, the MDD does not give detailed specifications for the content of these instructions.

Instructions for reuse

- Despite this clear requirement in the MDD, we hear complaints that the CSSD is confronted with:
 - No instructions at all
 - Instructions for procedures that are outdated
 - Instructions for processes that have a doubtful efficacy
 - Instructions for laborious and possible hazardous manual procedures
 - Instructions to use sterilization processes that are not available
 - Instructions to use a brand of detergent that is not sold in the Netherlands
- Fortunately, we have the standard ISO 17664 !?

EN/ISO 17664

**“Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices”
(2004)**

INTERNATIONAL
STANDARD

**ISO
17664**

First edition
2004-03-01

**Sterilization of medical devices —
Information to be provided by the
manufacturer for the processing of
resterilizable medical devices**

*Stérilisation des dispositifs médicaux — Informations devant être
fournies par le fabricant pour le processus de restérilisation des
dispositifs médicaux*

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Reference number
ISO 17664:2004(E)

© ISO 2004

General requirements, ISO 17664

- The manufacturer has to provide specifications for every detail of every step in the reprocessing procedure
- The recommended processes must be validated
- The manufacturer has to take into account:
 - The training and knowledge of the personnel
 - The available cleaning, disinfection and sterilisation processes
- Limitations on the reprocessing must be stated
 - Number of reprocessing cycles, or
 - A method to determine the lifespan of the medical device.

- But, will the manufacturer do all these things?

Dutch Ministry of Public Health

- Can we help the people in the CSSD?
- We think that instructions should be evaluated before the instrument is bought so that the CSSD can decide if they can reprocess the device or not.
- A systematic checklist may be helpful
- The Dutch Health Care Inspectorate gave us the order to write a checklist for the evaluation of instructions for reuse



The first draft

- Based on standard EN/ISO 17664
- Every single requirement in this standard was converted into a question
- The resulting checklist was very detailed and contained 96 questions
- Apart from the questions given by EN/ISO 17664 we asked whether the medical device could be reprocessed by the CSSD



First draft

- 10 persons evaluated 3 instructions for reuse of their own choice, using the draft checklist:
 - Good
 - Mediocre
 - Poor
- These persons were asked to give their opinion on the quality of the checklist.



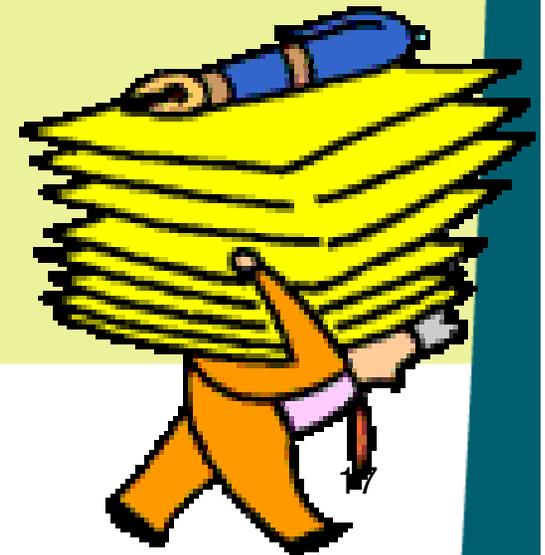
Results

- In total 26 checklists were completed
- 61% of the instructions was judged as inadequate
- Process parameters are missing or incomplete
 - Cleaning and disinfection, no process parameters at all
 - Only sterilisation temperature and time are given
- Nevertheless, in 54% of the checklists the CSSD indicated that they were able to reprocess the medical device.



Results

- Checklist was too long and contained too many details
- “I am not really interested whether the instructions for reuse meet the requirements in the standard.”
- “I want to know if I can reprocess the devices with the equipment and materials I have.”
- “We do not judge the reprocessing possibilities only from paper. We also examine the device itself.”
- “I wish that the supplier of the instruments would contact the CSSD before the instruments are delivered, so we can prepare and where necessary adapt the existing procedures.”



Problems in the instructions

- Most instructions available in Dutch, but poor translations, disregarding Dutch jargon; “thermal sterilised” instead of autoclaved, “Health and Safety laws” instead of ARBO.
- References to foreign national standards instead of NEN (EN and ISO) standards; e.g. AAMI, DIN.
- References to foreign national advisory committees “UK working party for TSE” instead of the Dutch counterpart (WIP).
- These foreign regulations may not be (are not) applicable in the Netherlands and may not be available or accessible.
- Non SI-units are used; °F instead of °C, Psi for steam pressure instead of kPa, inHG for vacuum pressure instead of kPa.

Problems in the instructions

- The prescribed processes are not standard available in the Dutch CSSDs, although this is required by ISO 17664.
 - Sterilisation at 132°C (USA) or 135°C (D) instead of 134°C.
 - Gravity displacement cycle instead of multiple vacuum.
 - Flash sterilisation cycle; abandoned for 20 years.
 - Validated sterilisation process according to AAMI standards; instead of specific process parameters.
 - Disinfection after cleaning is rarely mentioned, where this is standard procedure in Dutch CSSD.
 - One (D) manufacturer mentions disinfection at 93°C for 10 minutes, where 90°C for 5 minutes is standard.

Problems in the instructions

- Some manufacturers do not provide any information on the processes, but leave it up to the user or refer to the manufacturer of equipment or materials.
 - ... in a suitable process
 - A process validated by the hospital
 - ... using a suitable detergent
 - A process optimized for the cleaning
 - ... wrap in suitable packaging material
 - Hospital has to ensure that the process is suitable for the cleaning of the instruments.
 - According to the instructions of the WD manufacturer
 - According to the instructions of the detergent manufacturer

Second checklist

Taking into account the comments and wishes of the panel:

- Number of questions reduced to six key questions
- Per question guidance questions are given
- Taking into account the expertise, experience and willingness of the CSSD personnel
- Taking into account the standard procedures in the Netherlands



Second checklist

- Can the medical device be cleaned in an automated WD?
- Is an acceptable alternative method for manual cleaning and disinfection given?
- Are you convinced that the medical device can be adequately cleaned and disinfected?
- Can you check the proper functioning of the device after cleaning?
- Can you package the medical device?
- Can you sterilise the medical device?
- Final question: Can you reprocess the medical device in your CSSD? Yes / No

Second checklist

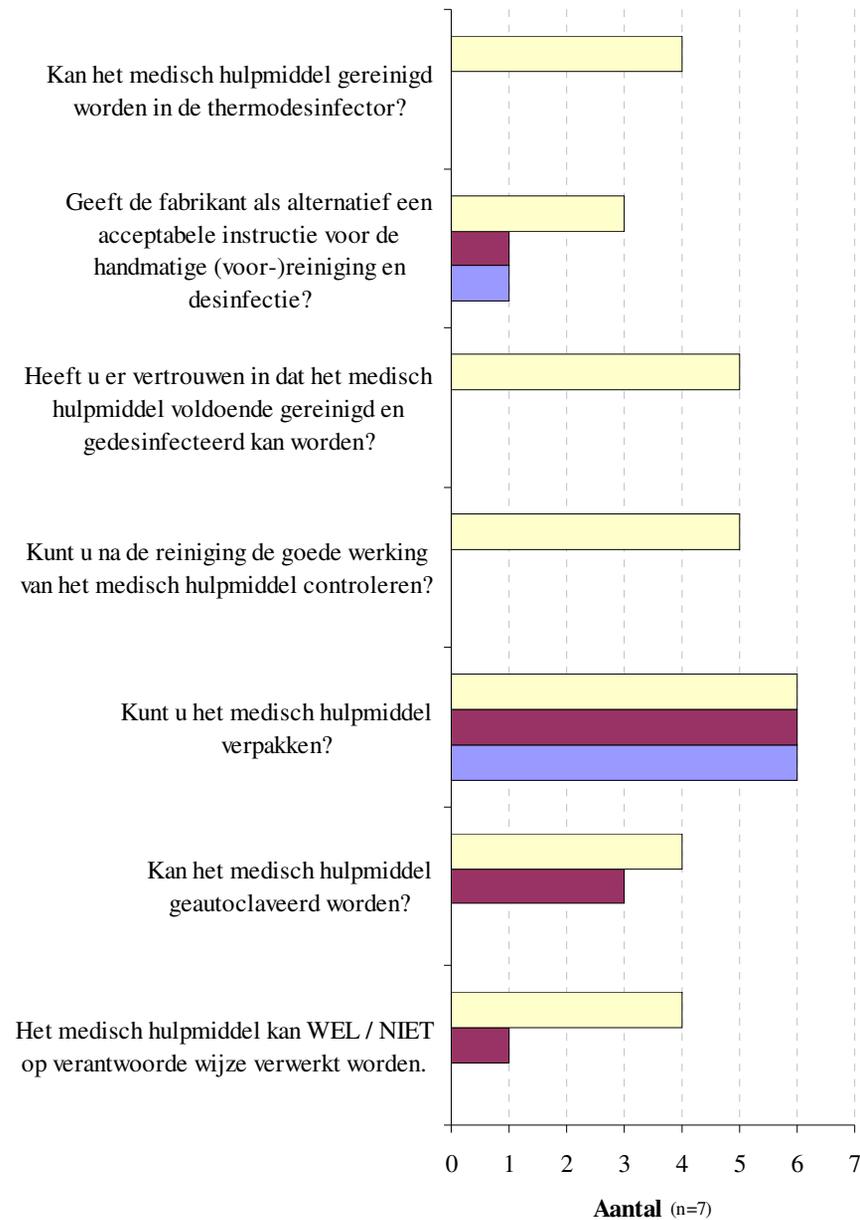
- RIVM selected 3 instructions for reuse
 - Good, mediocre, poor
 - These instructions were evaluated by all
 - The experts were again asked for their opinion about the quality checklist



Final checklist

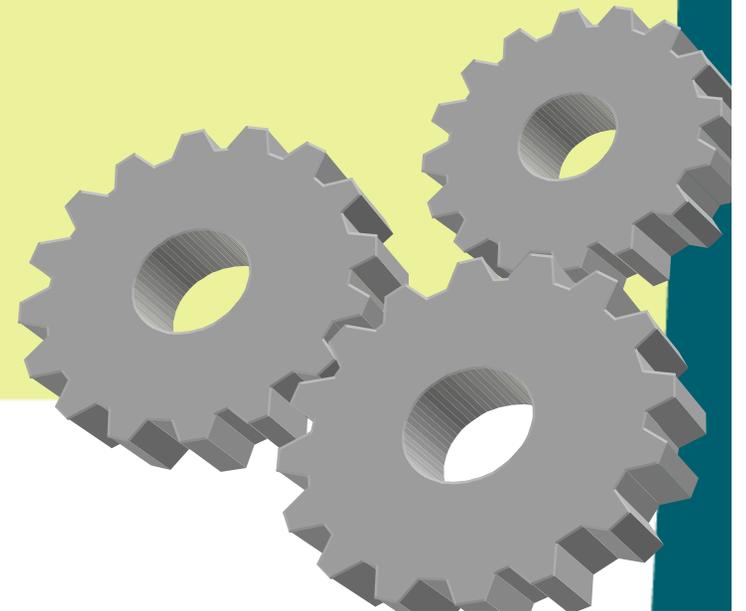
- Seven persons completed a checklist for each of the three instructions for reuse.
- This second version of the checklist was much more appreciated than the first one.
- A few minor corrections to the guidance questions led to the final version of the checklist.
- The final checklist was published in Central Service vol 14. 2006: 34-36 and is available from the RIVM website.

Score 'in orde'



Conclusions

- A checklist based on all the detailed requirements in ISO 17664 is too long and too detailed and therefore impractical.
- Nevertheless, 26 checklists show that the many of the instructions for reuse that were studied did not fulfill the requirements of ISO 17664.
- ISO 17664 is a valuable reference document that may help you in convincing the manufacturer to supply better instructions for reuse.



Conclusions

- The final checklist may be helpful to establish whether you can reprocess the device in your CSSD. The instructions for reuse should be evaluated before the device is purchased.
- You must avoid to be faced with a fait accompli; the device is purchased and used, and you cannot reprocess it.
- This means that the CSSD must be seriously involved in the purchasing procedure of reusable medical devices.



